

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARDY DIAGNOSTICS, INC.,)	
)	
Plaintiff, Counter-Defendant)	
)	
v.)	C.A. No. 24-1355 (JDW)
)	
IRHYTHM TECHNOLOGIES, INC.,)	JURY TRIAL DEMANDED
)	
Defendant, Counter-Plaintiff.)	

**DEFENDANT IRHYTHM TECHNOLOGIES, INC.'S ~~SECOND-THIRD~~
AMENDED COUNTERCLAIMS AND ANSWER [RESERVED] TO PLAINTIFF
BARDY DIAGNOSTICS, INC.'S ~~FIRST-SECOND~~ AMENDED COMPLAINT**

Defendant iRhythm Technologies, Inc. ("Defendant" or "iRhythm"), by and through its undersigned counsel, hereby answers the ~~First-Second~~ Amended Complaint ("~~FS~~AC") of Bardy Diagnostics, Inc. ("Plaintiff" or "Bardy") and asserts counterclaims as follows:

I. IRHYTHM'S COUNTERCLAIMS AGAINST BARDY

iRhythm asserts the following counterclaims against Bardy.

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising from Bardy's infringement of U.S. Patent Nos. 12,133,734 (the "'734 patent"), 12,245,859 (the "'859 patent"), 12,245,860 (the "'860 patent"), ~~and~~ 12,274,554 (the "'554 patent"), and 12,303,277 (the "'277 patent") (collectively, the "iRhythm Asserted Patents").

2. iRhythm is the owner by assignment of the '734 patent. A copy of the '734 patent is attached as Exhibit 1.

3. iRhythm is the owner by assignment of the '859 patent. A copy of the '859 patent

is attached as Exhibit 11.

4. iRhythm is the owner by assignment of the '860 patent. A copy of the '860 patent is attached as Exhibit 12.

5. iRhythm is the owner by assignment of the '554 patent. A copy of the '554 patent is attached as Exhibit 15.

~~5.6.~~ iRhythm is the owner by assignment of the '277 patent. A copy of the '277 patent is attached as Exhibit 18.

THE PARTIES

~~6.7.~~ iRhythm is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 699 8th Street, Suite 600, San Francisco, CA 94103.

~~7.8.~~ On information and belief, Bardy is a corporation organized and existing under the laws of the State of Delaware since 2013.

~~8.9.~~ On information and belief, Bardy has its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA 98005.

JURISDICTION AND VENUE

~~9.10.~~ This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq., including specifically 35 U.S.C. § 271.

~~10.11.~~ This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

~~11.12.~~ On information and belief, as a corporation organized and existing under the laws of the state of Delaware, Bardy has substantial and continuous contacts with Delaware and has committed acts of infringement in Delaware sufficient to confer personal jurisdiction over Bardy.

This Court also has personal jurisdiction over Bardy at least by virtue of Bardy filing the instant action in this Court.

~~12.~~13. On information and belief, Bardy is a commercial entity that makes, uses, advertises, offers for sale, imports, and/or sells ECG monitors and ECG monitoring services. On information and belief, Bardy manufactures, makes, uses, advertises, offers for sale, imports, and/or sells the Carnation Ambulatory Monitor (the “CAM patch”).

~~13.~~14. On information and belief, Bardy sells and offers to sell ECG monitors and ECG monitoring services, including the CAM patch, throughout the United States, including in this judicial district.

~~14.~~15. On information and belief, Bardy makes the CAM patch available to healthcare providers and patients in Delaware.

~~15.~~16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Bardy is incorporated in the State of Delaware and therefore resides in this judicial district.

BARDY AND BARDY’S CARNATION AMBULATORY MONITOR

~~16.~~17. On information and belief, Bardy is an ambulatory ECG monitoring solutions company founded in 2013, around 7 years after iRhythm was founded in 2006 and after iRhythm had already launched the Zio XT monitor. *See* <https://www.bardydx.com/>.

~~17.~~18. On information and belief, Bardy received FDA approval for the CAM patch no earlier than Dec. 22, 2014. *See* https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143067.pdf.

~~18.~~19. On information and belief, Bardy publicly launched and began commercializing the 2-day CAM patch in the United States no earlier than 2015.

~~19.~~20. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 2-day CAM patch in the United States.

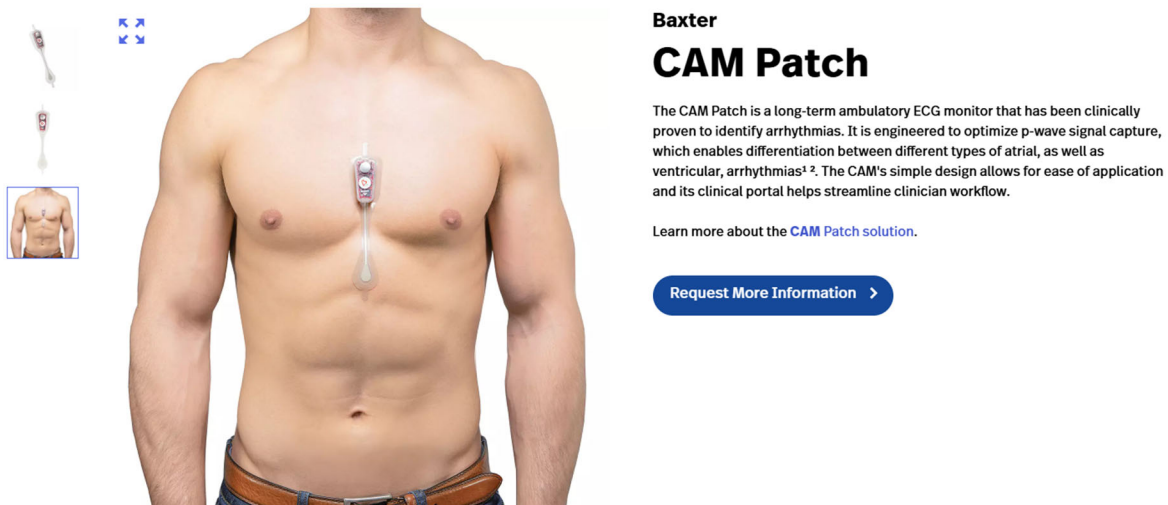
20-21. On information and belief, Bardy publicly launched and began commercializing the 7-day CAM patch in the United States no earlier than 2015.

21-22. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 7-day CAM patch in the United States.

22-23. On information and belief, Bardy publicly launched and began commercializing the 14-day CAM patch in the United States on or around January 23, 2020. *See* Exhibit 2, Bardy Diagnostics, Inc., “Bardy Diagnostics Announces Commercial Launch of the 14-day Carnation Ambulatory Monitor (CAM) Patch,” PR Newswire (Jan. 23, 2020), <https://www.prnewswire.com/news-releases/bardy-diagnostics-announces-commercial-launch-of-the-14-day-carnation-ambulatory-monitor-cam-patch-300991978.html>.

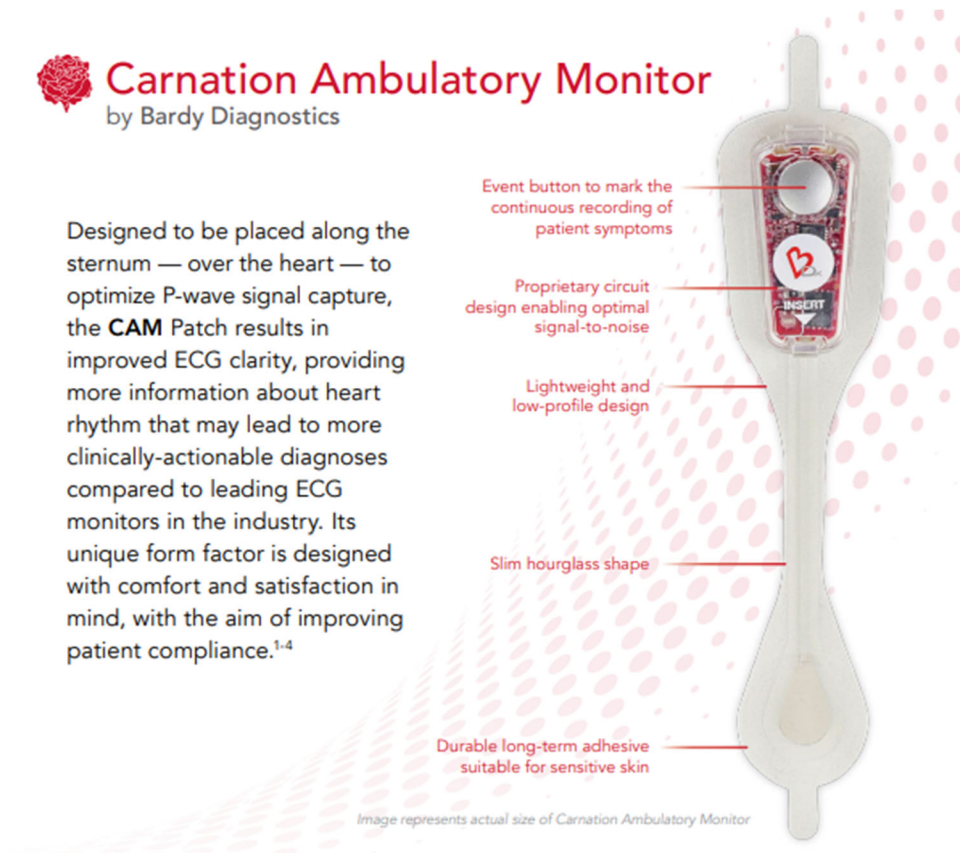
23-24. On information and belief, Bardy continues to manufacture, use, sell, import, and/or offer to sell the 7-day CAM patch in the United States.

24-25. The CAM patch is an ambulatory ECG monitor that adheres to a user’s chest. *See, e.g.,* Exhibit 3, <https://www.hillrom.com/en/products/cam-patch/>.



25-26. As shown below, the CAM patch includes electrodes that capture p-wave signals, “which enables differentiation between different types of atrial, as well as ventricular,

arrhythmias.” *Id.*; *see also* Exhibit 4, <https://www.bardydex.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>. The CAM patch includes a purportedly “proprietary circuit” in a housing that is electronically connected to an electrode located on the patch. Exhibit 5, <https://www.bardydex.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>.



26-27. On information and belief, and according to Bardy, the CAM patch provides a “[d]urable” adhesion that can last “[u]p to 2, 7, or 14 days.” *See* Exhibit 4.

Technical Specifications

13

TECHNICAL SPECIFICATIONS

ITEM	SPECIFICATION
Performance Characteristics	
ECG channels	1 channel
Recording capacity	Up to 2, 7, or 14 days
Recording format	Continuous
Service life	Up to 2, 7, or 14 days
Shelf life	24 months

27-28. On information and belief, and according to Bardy, the CAM patch “captures P-wave signals” from the heart using electrodes and transmits those to a purportedly “[p]roprietary circuit” located on the patch. Exhibit 5; *see also* Exhibit 6, https://www.bardydx.com/wp-content/uploads/2023/07/DN000697B-BDx_CAM_SpecSheet.pdf.

28-29. Given the facts alleged in this counterclaim, both stated above and set forth below and in Exhibits 7, 13, 14, 16, ~~and~~ 17, and 19, Bardy’s CAM patch directly infringes the claims of the iRhythm Asserted Patents, literally or under the doctrine of equivalents.

FIRST COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,133,734

29-30. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 28 of Section I of iRhythm’s Counterclaims and Answer.

30-31. The ’734 patent duly and legally issued on November 5, 2024.

31-32. iRhythm owns all right, title, and interest in the ’734 patent by assignment.

32-33. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 7, Bardy directly infringes at

least claim 1 of the '734 patent, either literally or under the doctrine of equivalents.

33:34. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '734 patent.

34:35. On information and belief, Bardy has had knowledge of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '734 patent.

35:36. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 7 to this counterclaim to Bardy's counsel.

36:37. On information and belief, despite having knowledge of the '734 patent and knowledge that the CAM patch infringes at least claim 1 of the '734 patent since at least February 28, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

37:38. Bardy has willfully infringed the '734 patent by continuing to make, use, import, offer to sell, and/or sell the CAM patch in the United States after having knowledge of the '734 patent and knowledge that the CAM patch infringes at least claim 1 of the '734 patent.

38:39. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

39:40. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '734 patent.

40:41. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined,

will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

[41.42.](#) As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

SECOND COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,245,859

[42.43.](#) iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 41 of Section I of iRhythm's Counterclaims and Answer.

[43.44.](#) The '859 patent duly and legally issued on March 11, 2025.

[44.45.](#) iRhythm owns all right, title, and interest in the '859 patent by assignment.

[45.46.](#) Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 13, Bardy directly infringes at least claim 1 of the '859 patent, either literally or under the doctrine of equivalents.

[46.47.](#) Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '859 patent.

[47.48.](#) On information and belief, Bardy has had knowledge of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '859 patent.

[48.49.](#) On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 13 to this counterclaim to Bardy's counsel.

[49.50.](#) On information and belief, despite having knowledge of the '859 patent and

knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

~~50.51.~~ Bardy has willfully infringed the '859 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '859 patent and knowledge that the CAM patch infringes at least claim 1 of the '859 patent.

~~51.52.~~ As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

~~52.53.~~ This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '859 patent.

~~53.54.~~ Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

~~54.55.~~ As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

THIRD COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,245,860

~~55.56.~~ iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 54 of Section I of iRhythm's Counterclaims and Answer.

~~56.57.~~ The '860 patent duly and legally issued on March 11, 2025.

~~57.58.~~ iRhythm owns all right, title, and interest in the '860 patent by assignment.

~~58.~~59. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 14, Bardy directly infringes at least claim 1 of the '860 patent, either literally or under the doctrine of equivalents.

~~59.~~60. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '860 patent.

~~60.~~61. On information and belief, Bardy has had knowledge of the '860 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '860 patent.

~~61.~~62. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '860 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 14 to this counterclaim to Bardy's counsel.

~~62.~~63. On information and belief, despite having knowledge of the '860 patent and knowledge that the CAM patch infringes at least claim 1 of the '860 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

~~63.~~64. Bardy has willfully infringed the '860 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '860 patent and knowledge that the CAM patch infringes at least claim 1 of the '860 patent.

~~64.~~65. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

~~65-66.~~ This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '860 patent.

~~66-67.~~ Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

~~67-68.~~ As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

FOURTH COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,274,554

~~68-69.~~ iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 67 of Section I of iRhythm's Counterclaims and Answer.

~~69-70.~~ The '554 patent duly and legally issued on April 15, 2025.

~~70-71.~~ iRhythm owns all right, title, and interest in the '554 patent by assignment.

~~71-72.~~ Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim charts attached as Exhibits 16 and 17, Bardy directly infringes at least claims 1 and 4 of the '554 patent, either literally or under the doctrine of equivalents.

~~72-73.~~ Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '554 patent.

~~73-74.~~ On information and belief, Bardy has had knowledge of the issued claims of the '554 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the allowed claims of U.S. Patent Application No. 18/936,888, now issued as the claims

of the '554 patent.

~~74.75.~~ On information and belief, Bardy has also had knowledge of the '554 patent since at least April 22, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '554 patent.

~~75.76.~~ On information and belief, Bardy has had knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 16 to this counterclaim to Bardy's counsel.

~~76.77.~~ On information and belief, Bardy has also had knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least April 22, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 17 to this counterclaim to Bardy's counsel.

~~77.78.~~ On information and belief, despite having knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

~~78.79.~~ On information and belief, despite having further knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least April 22, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

~~79.80.~~ Bardy has willfully infringed the '554 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent.

~~80.81.~~ As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a

reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

81-82. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '554 patent.

82-83. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

84. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

FIFTH COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,303,277

85. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 84 of Section I of iRhythm's Counterclaims and Answer.

86. The '277 patent duly and legally issued on May 20, 2025.

87. iRhythm owns all right, title, and interest in the '277 patent by assignment.

88. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 19, Bardy directly infringes at least claim 1 of the '277 patent, either literally or under the doctrine of equivalents.

89. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '277 patent.

90. On information and belief, Bardy has had knowledge of the '277 patent since at least May 20, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '277

patent.

91. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '277 patent since at least May 20, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 19 to this counterclaim to Bardy's counsel.

92. On information and belief, despite having knowledge of the '277 patent and knowledge that the CAM patch infringes at least claim 1 of the '277 patent since at least May 20, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

93. Bardy has willfully infringed the '277 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '277 patent and knowledge that the CAM patch infringes at least claim 1 of the '277 patent.

94. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

95. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '277 patent.

96. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

~~83-97.~~ As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

RELIEF REQUESTED

WHEREFORE, iRhythm respectfully requests the following relief:

- A. A judgment and order that Bardy has infringed the iRhythm Asserted Patents;
- B. An order preliminarily and permanently enjoining and restraining Bardy, its officers, directors, agents, servants, employees, licensees, attorneys, and all other persons acting under or through them, directly or indirectly, from infringing the iRhythm Asserted Patents;
- C. A judgment and order requiring that Bardy pay damages under 35 U.S.C. § 284, including an award up to three times iRhythm's damages, as well as prejudgment and post-judgment interest and costs and post-trial damages for any ongoing infringement;
- D. A judgment and order that this case is exceptional and awarding iRhythm its attorneys' fees, costs, disbursements, and interest, as provided by law, including under 35 U.S.C. § 285;
- E. A judgment that Bardy's infringement has been willful, and ordering Bardy to pay treble damages as provided by law; and
- F. Such other and further relief as the Court may deem just and equitable.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, iRhythm respectfully requests a trial by jury in this action for all issues triable by a jury.

II. ANSWER

[RESERVED]

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

OF COUNSEL:

J. David Hadden
Allen Wang
FENWICK & WEST LLP
801 California Street
Mountain View, CA 94041
(650) 988-8500

Melanie L. Mayer
FENWICK & WEST LLP
401 Union Street, 5th Floor
Seattle, WA 98101
(206) 389- 4510

Robert Edward Counihan
Daniel Rabinowitz
FENWICK & WEST LLP
902 Broadway, 18th Floor
New York, NY 10010
(212) 430- 2600

Brian P. Egan (#6227)
Lucinda C. Cucuzzella (#3491)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
ccucuzzella@morrisnichols.com

Attorneys for Defendant

| ~~April 25~~ June 2, 2025